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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,885	10/28/98	CUBICCIOTTI R	BDA-0038

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EXAMINER	
WARE, T	
ART UNIT	**PAPER NUMBER**
1615	14

DATE MAILED: 11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/171,885	Applicant(s) CUBICCIOTTI, ROGER S.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *13 August 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *13-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☒ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Receipt of amendment and response filed 8-13-00 is acknowledged. Claims 13, 14, 16, 18, 20, 22, 24, 26, and 28 have been amended as requested. claims 13- 29 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of "a drug bound to a synthetic receptor selected to bind said drug by a method selected from..." is unclear. As written, this may be understood to claim that combinatorial selection, monoclonal antibody selection and antibody engineering are methods by which the drug binds to a synthetic receptor while it appears that applicants are attempting to claim that the synthetic receptor is identified or is selected by either combinatorial selection, monoclonal antibody selection or antibody engineering. Correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morgan, Jr. et al (5,106,951; hereafter '951).

'951 discloses drug/carrier complexes and a method of administering a drug via a drug/carrier complex where a drug binds to a polymeric carrier to form a prodrug complex that is capable of allowing drug dissociation from the polymeric carrier such that the drug retains its ability to bind to a site on or within a target cell. Since '951 states that the drug's ability to bind to a higher affinity site on or within the target cell is retained (abstract; C4, L43-C5, L25; C8, L30-40; C18, L43-48), the conjugate of '951 binds preferentially to the "pathophysiologic receptor" (the higher affinity site on or within the target cell). '951 also discloses that the drug-conjugate is not exposed to derivatization conditions that might compromise the potency of the drug (i.e. the drug is immobilized and is protected from metabolism which would increase its half-life over administration of the drug alone) (C4, L43-50). '951 further discloses that targeting proteins may be attached to the conjugate.(C7, L10-19, 30-37). The carriers of '951 may also bind more than one drug (C10, L62-66). The methods used to identify the conjugate are not considered patentably distinct as they are intended use limitations. Furthermore, the antibodies of '951 would be readily identifiable by the instant methods.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 13-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan, Jr. et al. (5,106,951; hereafter '951).

'951 teaches drug/carrier complexes and a method of administering a drug via a drug/carrier complex where a drug binds to a polymeric carrier to form a prodrug complex that is capable of allowing drug dissociation from the polymeric carrier such that the drug retains its ability to bind to a site on or within a target cell. Since '951 states that the drug's ability to bind to a higher affinity site on or within the target cell is retained (abstract; C4, L43-C5, L25; C8, L30-40; C18, L43-48), the conjugate of '951 binds preferentially to the "pathophysiologic receptor" (the higher affinity site on or within the target cell). '951 also discloses that the drug-conjugate is not exposed to derivatization conditions that might compromise the potency of the drug (i.e. the drug is immobilized and is protected from metabolism which would increase its half-life over administration of the drug alone) (C4, L43-50). '951 further discloses that targeting proteins may be attached to the conjugate.(C7, L10-19, 30-37). The carriers of '951 may also bind more than one drug molecule (C10, L62-66). The methods used to identify the conjugate are not considered patentably distinct as they are intended use

limitations. Furthermore, the antibodies of '951 would be readily identifiable by the instant methods.

'951 does not specifically state that the carriers of '951 may bind multiple drugs wherein the drugs are different. '951 does state that the carriers have multiple drug-binding regions capable of binding multiple drug molecules. Therefore, it would be obvious to one skilled in art at the time of the invention to design the conjugates of '951 wherein the domains would be different would be capable of binding more than one drug where the drugs are different with the expectation that administering more than one drug to treat a condition would result in an additive treatment effect with the motivation of protecting the drug against metabolism or other factors that might reduce potency.

Response to Arguments

6. Applicant's arguments filed 8-13-00 have been fully considered but they are not persuasive. Applicants argue that Morgan, Jr. et al (5,106,951; hereafter '951) does not apply to the instant claims, since the instant claims require an "immobilized prodrug complex" and the term "immobilized" is a term of the art meaning "insolubilized by attachment to an insoluble matrix or solid support." However, it is submitted that this is only one meaning of the term "immobilized" and as such language is insufficient to overcome the rejection of claims 13-29 under 35 U.S.C. 102(b) as being clearly anticipated by Morgan, Jr. et al (5,106,951' hereafter '951) or the rejection of claims 13-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan, Jr. et al. (5,106,951; hereafter '951).

Merriam-Webster's Collegiate Dictionary (10th edition) defines the term immobilize as "to make immobile a: to prevent freedom of movement or effective use of b: to reduce or eliminate motion of by mechanical means or by strict bed rest c: to withhold (money or capital) from circulation. Roget's II The New Thesaurus provides the expression "tie up" as an alternative to the word immobilize. Given these definitions and alternative, it is submitted that the term immobilize has meaning other than that submitted by applicants. It is further submitted that the drug and conjugate of '951 are bound to one another or alternatively are "tied up together" meeting the alternative definitions of "immobilized."

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) for regular communications and (703) for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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November 2, 2000